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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,967	09/25/2002	Sing N. Chin	18242-501 NATL	9961

7590 03/30/2005
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EXAMINER

SAUCIER, SANDRA E

ART UNIT PAPER NUMBER

1651

DATE MAILED: 03/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,967

Applicant(s)

CHIN ET AL.

Examiner

Sandra Saucier

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 31-33 is/are allowed.
- 6) ☒ Claim(s) 16-23 and 27-30 is/are rejected.
- 7) ☒ Claim(s) 24-26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 September 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Claims 1–36 are pending. Claims 16–33 are considered on the merits. Claims 1–15, 35, 36 are withdrawn from consideration as being drawn to a non-elected invention.

Election/Restriction

Applicant's election without traverse of Group II in Paper No. 2/14/05 is acknowledged.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 16–23, 27–30 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,541,294 [A] in combination with the Tosoh Bioscience Catalog [U] or Cutler [V].

The claims are directed to a process for reusing an affinity column having a ligand for isoagglutinin to remove an agglutinin from a blood derived composition comprising:

- (a) providing a resin linked to an antigen for isoagglutinin,
- (b) washing the resin with a buffer to form a regenerated resin,
- (c) contacting the regenerated resin with a blood-derived composition allowing complexing the regenerated resin with the isoagglutinin from the blood-derived composition to form an isoagglutinin free blood-derived composition,

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- (d) collecting the isoagglutinin free blood-derived composition,
- (e) repeating steps b-d.

US 5,541,294 discloses a method of separating isoagglutinin from plasma comprising:

- (a) providing an affinity column having ToyoPearl polyalkylmethacrylic resin linked to antigen B antibody,
- (b) washing the resin with PBS pH 7.4,
- (c) contacting the resin with plasma,
- (d) collecting the isoagglutinin-free plasma.

The reference lacks the description of regenerating the resin for reuse and the use of the specific Toyopearl methacrylate resin, AF-Carboxy.

Tosoh Bioscience Catalog describes the cleaning process for Toyopearl methacrylate resin which suggest running 1M NaCl, 6M urea and then the starting buffer for cleaning (regeneration) of the affinity column. The number of times such a column can be cleaned is not limited by the reference. The catalog also describes the several polymethacrylate resins used for affinity chromatography sold under the name "Toyopearl", which include Toyopearl AF-Carboxy-650M.

Cutler teach a general method of purification of a target protein which includes regeneration of the affinity column with a regeneration buffer containing salt and 8M urea. The number of times a column can be cleaned is not limited by the reference.

The substitution of a specific Toyopearl methacrylate affinity column resin, such AF-Carboxy derivitized for the generically disclosed Toyopearl methacrylate resin of US '294 would have been obvious when the Tosoh Bioscience Catalog, which teach several affinity column polymethacrylate resins, including AF-Carboxy, AF-Amino, AF-Tresyl, etc., was taken in view of US

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'294. This appears to be a substitution of equivalents in the absence of evidence to the contrary.

The addition of a regeneration step to the method of US '294 would have been obvious when taken with Tosho Bioscience Catalog or Cutler, both of which teach the use of a cleaning/regeneration step in order to reuse the column.

One of ordinary skill in the art would have been motivated at the time of invention to modify the method of the primary reference in order to obtain the results as suggested by the references, namely regeneration and cleaning of the matrix in order to reuse it with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Allowable Subject Matter

Claims 31–33 are allowed.

Claims 24–26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims. a copy of such copending claims is requested in response to the office action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday, Tuesday, Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sandra Saucier
Primary Examiner
Art Unit 1651
March 28, 2005